



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Ulrich Speck et al.

Serial No.: 10/528,577

Group Art Unit: 3764

Filed: March 21, 2005

Examiner: Cris Loiren Rodriguez

For: MEDICAL DEVICE FOR DISPERSING MEDICAMENTS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§ 1.56, 1.97 and 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**Timing and Fees**

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- a final rejection under 37 C.F.R. 1.113;
  - termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).

☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:

- ☐ a final action under 37 C.F.R. § 1.113;
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- ☐ OR a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

Statements Under 37 C.F.R. 1.97(e)

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

Cited Materials

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☐ Not required by 37 CFR § 1.98.
- ☒ Copies of the materials listed are attached (except for the foregoing).

### Non-English Language References

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).
- ☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:
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A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
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- ☐ Translation of other relevant information on foreign search report

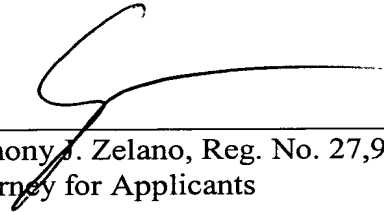
### Other Information

#### Payment of Fees Due (If Any):

- ☐ A check for \$\_\_\_\_\_ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.

☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account #13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,



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Attorney Docket No.: WEICKM-0044

Date: August 24, 2006

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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### Complete if Known

Application Number	10/528,577
Filing Date	March 21, 2005
First Named Inventor	Ulrich Speck et al.
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	WEICKM-0044

### U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	5,554,182		Dinh et al.	09-10-1996
	A2	6,491,938	B2	Kunz et al.	12-10-2002
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	A17	5,051,257		Pietronigro	09-24-1991
	A18	6,544,544		Hunter et al.	04-08-2003

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached. Number refers to English language corresponding family member.

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	EP	0829238	B1	Gray Lary Banning	09-13-2000		
	B2	WO	2004/028610	A2	Ulrich Speck et al.	04-08-2004		
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	B20	WO	97/26862		Schering AG	01-1997		
	B21	DE	4446694		Schering AG	12-1994		
	B22	WO	96/38183		Ramot Univ. Israel	05-1995		

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### NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	Pierre Signore et al., "Complete Inhibition of Intimal Hyperplasia by Perivascular Delivery of Paclitaxel in Balloon-injured Rat Carotid Arteries," LABORATORY INVESTIGATIONS, vol. 12, no. 1, January 2001, pp. 79-88.	
	C2	File History of US Provisional Application 60/395,434 filed July 12, 2002.	
	C3	File History of US Provisional Application 60,244,446 filed October 31, 2000.	
	C4	Ran Kornowski et al., "Slow-Release Taxol Coated GRIT™ Stents Reduce Neointima Formation in a Porcine Coronary In-Stent Restenosis Model," 70 <sup>th</sup> Scientific Sessions of the American Heart Association, Nov. 9-12, 1997.	
	C5	Alan W. Heldman et al., "Paclitaxel Stent Coating Inhibits Neointimal Hyperplasia at 4 Weeks in a Porcine Model of Coronary Restenosis," CIRCULATION, May 8, 2001, pp. 2289-2295.	
	C6	Department of Health and Human Services NOTICE OF INTRAMURAL RESEARCH PROJECT, October 1, 1993-September 30, 1994; "Molecular Strategies to Treat Restenosis," 4 pp.	
	C7	Department of Health and Human Services NOTICE OF INTRAMURAL RESEARCH PROJECT, October 1, 1994-September 30, 1995, "Local Delivery of Therapeutic Agents for the Prevention of Restenosis," 6 pp.	
	C8	Teruo Inoue et al., "Comparison of Activation Process of Platelets and Neutrophils After Coronary Stent Implantation Versus Balloon Angioplasty for Stable Angina Pectoris," THE AMERICAN JOURNAL OF CARDIOLOGY, vol. 86, November 15, 2000, pp. 1057-1062.	
	C9	Eric K. Rowinsky et al., "Paclitaxel (Taxol)," Alastair J.J. Wood, ed. "Drug Therapy," THE NEW ENGLAND JOURNAL OF MEDICINE, vol. 332, no. 15, April 13, 1995, pp. 1004-1014.	
	C10	Dorothea I. Axel et al., "Paclitaxel Inhibits Arterial Smooth Muscle Cell Proliferation and Migration In Vitro and In Vivo Using Local Drug Delivery," CIRCULATION, 1997, vol. 96, pp. 636-645.	
	C11	Bruno Scheller et al., "Acute Cardiac Tolerance of Current Contrast Media and the New Taxane Protaxel Using Iopromide as Carrier During Porcine Coronary Angiography and Stenting," Investigative Radiology, vol. 37, no. 1, pp. 29-34.	
	C12	MARTIN OBERHOFF ET AL., "Local delivery of Paclitaxel using the double-balloon perfusion catheter before stenting in the porcine coronary artery," 2001, Catheterization and Cardiovascular Interventions, pages 562-568, vol. 53.	
	C13	CHRISTOPHER J. CREEL ET AL., "Arterial Paclitaxel distribution and deposition," Circulation Research, 28 April 2000, pages 879-884.	
	C14	DR. KARSCH, "Lokale Applikation von Paclitaxel mit dem Schneider-Doppelballon," nach experimenteller Stentimplantation an den Koronararterien des Schweines, Gießen 2001.	
	C15	TORU KATAOKA ET AL., "7-Hexanoyltaxol-Eluting Stent for prevention of Neointimal Growth," Circulation, 1 October 2002, pages 1788-1793.	
	C16	ROGER CHARLES ET AL., "Ceramide-coated balloon catheters limit neointimal hyperplasia after stretch injury in carotid arteries," Circulation Research, 18 August 2000, pages 282-288.	

C17	FRANK D. KOLODIE ET AL., "Local delivery of ceramide for restenosis: Is there a future for lipid therapy? Circulation Research, 18 August 2000, pages 264-267.	
C18	JOHNATHAN D. ADAMS ET AL., "Taxol: a history of pharmaceutical development and current pharmaceutical concerns," Journal of the National Cancer Institute Monographs, 1993, pages 141-147, no. 15.	
C19	JACKSON ET AL., "Current usage of contrast agents, anticoagulant and antiplatelet drugs in angiography and angioplasty in the UK," Clinical Radiology, 1995, pages 699-704, vol. 50, no. 10.	
C20	Elsevier Science Publishers, Amsterdam, NL; JACKSON D.M. A. et al Current usage of contrast agents, anticoagulant and antiplatelet drugs in angiography and angioplasty in the UK. retrieved from STN Database accession no. 95327068 XP002226116	
C21	International Preliminary Examination Report for PCT/DE2003/002871.	
C22	International Preliminary Examination Report for PCT/DE2001/04782.	
C23	International Search Report for EP 06 00 1041, Search Date: April 11, 2006.	
C24	International Search Report for EP 06 00 1042, Search Date: April 10, 2006.	
C25	International Search Report for EP 06 00 1040, Search Date: April 11, 2006.	
C26	International Search Report for PCT/DE01/04782, Search Date: December 27, 2002.	
C27	International Search Report for PCT/EP03/10480, Search Date: February 20, 2004.	
C28	International Search Report for PCT/DE03/02871, Search Date: February 17, 2004.	

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